K082845

Alcon

5. PREMARKET NOTIFICATION 510(k) SUMMARY

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

Michael Buenger
Associate Director, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76132
Phone: (817) 551-6810
Fax: (817) 551-4630

Device Subject to this 510(k):

Trade Name:	*Infiniti® Vision System*
Common Name:	Phacofragmentation System
Classification Name:	Phacofragmentation System (per 21 CFR 886.4670)

5.1. Predicate Devices:

The legally marketed devices(s) to which we are claiming equivalence to are:

510(k) Number	Device
K021566	Infiniti® Vision System
K981116	Sovereign* Cataract Extraction System
K063583	Alcon Vision System (Constellation)
K911808	Gemini Ophthalmic Surgery System (Marketed as the Series 20000® Legacy® (STTL) and Accurus®)

5.2. Device Description

The *Infiniti® Vision System with OZil® IP* is an enhanced version of the *Infiniti® Vision System* (K021566) that is modular in design and incorporates both the *OZil® IP* feature and the *Infiniti® UltraVit™ Vitrectomy Probe* and its associated software.

5.3. *Indications for Use:*

The *Infiniti® Vision System with OZil® IP* is indicated for emulsification and removal of cataracts, vitreous aspiration and cutting associated with anterior vitrectomy, and bipolar coagulation.

5.4. *Brief Summary of Nonclinical test and Results:*

Safety tests of the *Infiniti® Vision System with OZil® IP* have demonstrated its compliance with applicable requirements of the following standards:

Standard #	Title
60601-1: 2003 UL (Equivalent to IEC 60601-1: 1998 with A1: 1991, A2: 1995)	Medical Electrical Equipment, Part 1 – General Requirements for Safety
60601-1-2 :2001 IEC	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility–Requirements and test.
60601-1-4:2000 IEC	Medical Electrical Equipment, Part 1: General Requirements for Safety. 4. Collateral standard: Programmable electrical medical systems.
60601-2-2: 1998 IEC	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment

Biocompatibility evaluations of materials coming in contact with the patient or patient fluid path have been performed to the following standards:

Standard #	Title
10993-1: 2003 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing
10993-5: 1999 AAMI / ANSI / ISO	Biological Evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
10993-7: 1995 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices -- Part 7: Ethylene Oxide Sterilization Residuals
10993-10:2002/A1:2006 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
10993-11:2006 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices -- Part 11: Tests for systemic toxicity

Standard #	Title
10993-12:2007 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices -- Part 12: Sample Preparation and Reference Materials

The *Infiniti® UltraVit™ Vitrectomy Probe* is provided sterile and intended for single use only. This product is EtO sterilized and the process has been validated per AAMI/ ISO 11135:2007: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. Reusable handpieces are provided non-sterile. Validated reprocessing instructions for cleaning, sterilization and re-use of the handpieces are provided in the Directions for Use of the product.

Technological characteristics affecting clinical performance are similar to that of predicate devices previously listed. The *Infiniti® Vision System with OZil® IP* has been developed and will be manufactured in compliance with section 21 CFR 820 and ISO 14971:2003. Non-clinical testing noted above has demonstrated that the functional requirements have been met and that the device is equivalent to the predicate device.

Trademark References:

*SOVEREIGN is a registered trademark of Allergan, Inc. Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alcon Research, Ltd.
c/o Michael Buenger
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

FEB 12 2009

Re: K082845
Trade/Device Name: Infiniti® Vision System with Ozil® IP
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: January 12, 2008
Received: January 13, 2008

Dear Mr. Buenger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

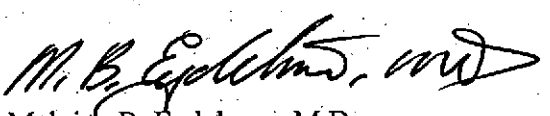
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082845

Device Name: *Infiniti® Vision System with OZil® IP*

Indications for Use:

The *Infiniti® Vision System with OZil® IP* is indicated for emulsification and removal of cataracts, vitreous aspiration and cutting associated with anterior vitrectomy, and bipolar coagulation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K082845